

### **Remarks**

Applicant thanks the Examiner for withdrawing the §102(b) rejection and for accepting the replacement drawings.

Claims 18-20, 25-42 and 51-58 are pending in the application. Claims 18, 38 and 42 are independent. Claim 18 has been amended. The existence of the word “moist” in claim 18 is due to a word processing error. When the claim was amended to “more humid”, the word “moist” was not properly deleted. Applicant respectfully submits that the amendment to claim 18 to remove the redundant word does not change the scope of the claim in any manner. For this reason, the available scope of equivalents under the doctrine of equivalents should not be decreased.

Reconsideration is respectfully requested.

### **I. Claim Rejections -35 USC § 103**

1. Claims 18-20, 25, 27, 33, are 38 are rejected, in the alternative, under 35 U.S.C. 103(a) as obvious over Green in view of Ding et al. (6,541,020).

Green discloses a therapeutic dental delivery device (fig. 1) comprising a liquid oral therapeutic dental composition (column 1 line 67), a dispenser comprising an applicator of a brush (column 1 line 14), an activator 32 coupled to the applicator of a push button mechanism and a reservoir 30 located in the device proximate the activator and configured to store the composition, a cap 14 having an open end terminating at a position between the activator and the applicator, the activator is configured to dispense the composition from the reservoir to the applicator.

Green discloses the therapeutic dental delivery device that shows the limitations as described above, however, Green does not explicitly show the composition that increases in viscosity in a more humid environment.

Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel (moisture or temperature responsive) composition that increase in viscosity (col. 15, 6-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Green in order to have a composition that can be easily dispensed and provide controlled release of therapeutic agent in view of Ding et al. Ding et al. show the composition comprising a moisture responsive gel carrier and a therapeutic agent, and it would have been obvious matter of choice to have a compound in salt form in the composition. The gel carrier comprises polymer complex comprising carboxypolymethylene and polyvinylpyrrolidone (column 13 lines 56-60).

Applicant respectfully traverses this rejection.

Applicant agrees with the Examiner that Green does not explicitly show a composition that increases in viscosity in a more humid environment, as recited in claim 18.

Ding et al. disclose "carrier hydrogel compositions of the invention are compositions comprising a polymer material that forms a hydrogel at physiological temperatures and a polypeptide which is either T20 or T1249. The carrier hydrogel compositions of the invention are ideally suited for administering the specific peptides, referred to as T20 and T1249, which are described herein, as well as derivatives of the T20 and T1249 peptides described herein." See Col. 2, Line 54-64. "The carrier hydrogel compositions comprise gelling materials that possess a reverse thermal gelation property, and at least one peptide, i.e., T20, T1249 or a derivative thereof. The carrier hydrogel compositions exist as liquid, aqueous solutions at temperatures that are below physiological temperatures. However, when the gelling materials are exposed to physiological temperatures (e.g., temperatures of about 37 degree C.) they form a

polymer gel which is biodegradable or at least bioerodible. Such carrier hydrogel compositions can be stored indefinitely in an aqueous state. The carrier hydrogel composition can then be administered to a patient in liquid form, e.g., by subcutaneous injection. Upon administration, the carrier hydrogel composition is heated to the patient's body temperature and forms a polymer gel which then acts as a sustained-release matrix for the peptides." See Col. 2, Line 65 to Col.3, Line 14. "Aqueous solutions of these polymers form micelles (microscopic spheres incorporating water) at low concentrations, and turn into thick continuous gels at higher concentrations (e.g., approximately 20-30% by weight) and elevated temperature (e.g., approximately 30.degree. C.)" (Emphasis added). See Col. 6, Line 35-40. Thus, while Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel, they do not teach a composition that increases in viscosity in a more humid environment, i.e., less concentrated environment, as the concentration of a polymer in a more humid environment is always lower than in a drier environment due to dilution, contrary to the Examiner's contentions.

In general, a composition decreases in viscosity as it becomes less concentrated, i.e., when exposed to a more humid environment. Therefore, Ding et al.'s disclosure that "solutions of these polymers form micelles (microscopic spheres incorporating water) at low concentrations, and turn into thick continuous gels at higher concentrations (Emphasis added) (e.g., approximately 20-30% by weight) and elevated temperature (e.g., approximately 30.degree. C.)", is teaching away from the present invention of a composition that increases in viscosity in a more humid environment, i.e., lower concentration environment.

As for claim 38, Green also does not disclose or teach "a polymer complex including carboxypolymethylene and polyvinylpyrrolidone and a water soluble salt", as recited in claim 38, which recites in relevant part "a liquid oral

therapeutic dental composition comprising a moisture responsive gel carrier and...the gel carrier comprises a polymer complex including carboxypolymethylene and polyvinylpyrrolidone and a water soluble salt" (Emphasis added). Ding et al may have disclosed gel carriers from a long listing of candidates, namely, "sugars, including lactose, sucrose, trehalose, mannitol or sorbitol; cellulose preparations such as, for example, maize starch, wheat starch, rice starch, potato starch, gelatin, gum tragacanth, methyl cellulose, hydroxypropylmethyl-cellulose, sodium carboxymethylcellulose, and/or polyvinylpyrrolidone (PVP)", but Ding et al. are only concerned with a carrier that can become more viscous at higher concentrations, as noted above. It would not have been an obvious matter of choice to have chosen a compound in salt form in the composition, especially since a salt form, as the Examiner names it, has the opposite property being sought by Ding et al., i.e., increase in viscosity in a more humid environment. See column 13, lines 56-60.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Applicant respectfully submits that since Ding et al.'s disclosure teaches the normal property of increasing in viscosity in drier conditions, i.e., increasing viscosity when increasing concentration, which has the inverse property of the composition of the present invention. Thus, Ding et al. do not supply the deficiencies of Green. Therefore, claims 18 and claim 38 are patentable over Green (5,829,976) in view of Ding et al. (6,541,020).

Claims 19, 20, 25, 27, and 33 are dependent from claim 18, and are also rejected under 35 U.S.C. 103(a) as obvious over Green in view of Ding et al. While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that this rejection is moot in view of the remarks made in connection with independent claim 18 above. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features which further distinguish them from the cited references. Therefore, dependent claims 19, 20, 25, 27 and 33 are also in condition for allowance.

Applicant respectfully requests that the rejection of claims 18-20, 25, 27, 33 and 38 under 35 U.S.C. 103(a) as being unpatentable over Green (5,829,976) in view of Ding et al. (6,541,020) be withdrawn. Reconsideration is respectfully requested.

2. Claims 18-20, 26, 28-30, 32, 33, 38, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. Grace discloses a therapeutic dental delivery device comprising a dental composition (page 2 line 50), an applicator 30 of a brush, an activator coupled to the applicator of a twist mechanism and a reservoir 26 located in the device proximate the activator and configured to store the composition, the activator is configured to dispense the composition from the reservoir to the applicator; however, Grace does not show a cap. Marx teaches a dental device comprising a cap for covering the applicator having an open end. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the device with the cap of Marx in order to protect the brush from dust and impurities in view of Marx. It would have been obvious to one of ordinary skill in the art made as to the specific activator, since

interchanging of twist mechanism in the device with a push button involves only routine skill in the art and Grace suggests other mechanical embodiments. The modified device does not show composition that increases in viscosity in the environment. Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel (moisture or temperature responsive) composition that increase in viscosity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Grace and Marx in order to have a composition that can be easily dispensed and provide controlled release of therapeutic agent in view of Ding et al. Ding et al. show the composition comprising a moisture responsive gel carrier and a therapeutic agent, and it would have been obvious matter of choice to have a compound in salt form in the composition. The gel carrier comprises polymer complex comprising carboxypolymethylene and polyvinylpyrrolidone (column 13 lines 56, 60).

Applicant respectfully traverses the rejection.

Grace discloses a fountain brush having a reservoir for receiving a replaceable refill cartridge 26 containing plastic or other material to be delivered to the bristles through a hollow shank by extrusion. See page 1, lines 11-19. A plunger has a plunger head 33 which is tapered to be pressed against the walls of the cartridge 26, and a plunger rod 34 having external threads for screwing the plunger rod 34 into the cartridge 26. (Emphasis added). See pages 2-3. "The plunger rod 34 is slotted longitudinally at its rear end ... whereby the rear end of the plunger is resilient so that the front end may be placed against a table ... so that pressure exerted forwardly on the cap 40 will cause the threaded feed barrel 39 to slip over the threads 37, thereby giving a quick turn of the plunger rod 34 to the rear position for another operation." (Emphasis added). See page 2, lines 113-125. Grace also discloses that "the threads 37, 28 in practice have a pitch such that

one turn of the cap 40 will cause a sufficient quantity of the paste or the like to be extruded to answer for a single service” (page 2, column 2, line 126 to page 3, column 1, line 1). Thus, not only does Grace not show a cap, or disclose a liquid oral therapeutic dental composition, said therapeutic dental composition comprises a moisture or temperature responsive composition that increases in viscosity in a more humid environment (Emphasis added), as admitted by the Examiner, Grace also does not disclose an activator such as a push button click mechanism or a twist and ratchet mechanism, etc.

Marx discloses a protective cover for a tooth brush. Since Marx is only cited by the Examiner to teach a cap for covering the applicator, the deficiencies in Grace are not supplied by Marx, for the reasons noted above.

The Examiner further cites Ding et al. to show a composition that increases in viscosity in a moist environment. As noted above, while Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel, Ding et al. do not teach a composition that increases in viscosity in a more humid environment. Ding et al. teach a gel that increases in viscosity as it increase in concentration and thus teach away from the present invention as the concentration of the polymer in a more humid environment is lower. Thus, the deficiencies of Grace is not supply by Marx and Ding et al.. Therefore, Grace in view of Marx and further in view of Ding et al. does not establish a *prima facie* case of obviousness, as set forth in MPEP §2142 and claim 18 is patentable over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020).

Similarly, Applicant respectfully submits that Grace in view of Marx and further in view of Ding et al. does not teach the invention of claim 38, which recites, in relevant parts, “a liquid oral therapeutic dental composition comprising a moisture responsive gel carrier and...the gel carrier comprises a

polymer complex including carboxypolymethylene and polyvinylpyrrolidone and a water soluble salt”, as noted above. (Emphasis added)

As admitted by the Examiner, the modified device (Grace in view of Marx) does not show a composition that increases in viscosity in a more humid environment (Emphasis added). Furthermore, as illustrated above, Ding et al. also do not teach a “composition comprising a moisture responsive gel carrier and...the gel carrier comprises a polymer complex including carboxypolymethylene and polyvinylpyrrolidone and a water soluble salt”. (Emphasis added) Therefore, claim 38 is also patentable over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020).

Claims 19-20, 26, 28-30, 32, 33, and 41 are dependent from claims 18 and 38, respectively, and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020). While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that their rejections are moot in view of the remarks made in connection with independent claims 18 and 38. The dependent claims include all of the limitation of the base claim and any intervening claims, and recite additional features which further distinguish the claims from the cited references. Therefore, claims 19-20, 26, 28-30, 32, 33, and 41 are also patentable under 35 U.S.C. 103(a) over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020).

Applicant respectfully requests that the rejection of claims 18-20, 26, 28-30, 32, 33, 38 and 41 over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. (6,541,020) be withdrawn. Reconsideration is respectfully requested.



3. Claims 34-37, 39, 40, 42, and 51-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green in view of Ding et al. and further in view of Matthews et al. (2003/0232310).

The modified device of Green and Ding et al. discloses a device that shows the limitations as described above; however, Green does not show the composition comprising therapeutic agent of peroxide. Matthews et al. teach a device comprising a liquid oral therapeutic dental composition comprising therapeutic agent of hydrogen peroxide or carbamide peroxide [0020]-[0022]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Green to have the therapeutic agent of Matthews et al. in order to whiten or bleach one or more teeth. Matthews et al. teach having instructions in order to show how to use the composition.

Applicant respectfully traverses the rejection.

Applicant again agrees with the Examiner that Green does not show the composition, etc.

Claims 18 and 38 are patentable over Green in view of Ding et al., as noted above. Contrary to the Examiner's contention, the modified device of Green in view of Ding et al. at best teaches away from the device of the present invention, as noted above. Likewise, claim 42 is also patentable over Green in view of Ding et al., for at least the same reasons as noted for claim 38.

Matthews et al. discloses a wand for applying a whitening composition to one or more tooth. See paragraph [0003]. "(T)he invention involves the further step of applying the whitening composition to the wand applicator 10. This step may be achieved by bringing the wand applicator 10 into contact with the whitening composition, for instance by dipping the stem member 30 of the wand applicator 10 into the whitening composition." See paragraph [0017]. (Emphasis added). Paragraphs [0020]-[0022] teach that a "relatively sticky material may be

included in the whitening composition to thicken the composition and act as a tackifying agent. This sticky material may be a polymer and may be selected from the group of carbomers known to resist degradation in the presence of peroxides and/or other whitening agents. Suitable carbomers are those that are safe for oral use and will not significantly inhibit whitening. Carbomers generally include acrylic acid backbones and small amounts of polyalkenyl polyether crosslinking agents. A suitable material is carboxypolymethylene. Carboxypolymethylene can be used to form a glue-like dental whitening composition that itself can act as an adhesive such that the composition tends to remain against a person's teeth. This tackifying agent may be present in an amount from about 0.5 to about 3 weight percent." See paragraph [0021]. "Carboxypolymethylene includes vinyl polymers having active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the tradename CARBOPOL. Carboxypolymethylene is also generally known as carbomer. Different embodiments of the invention may utilize a variety of forms of salts of carboxypolymethylene including complete salts (where all of the acid groups have been neutralized) or partial salts (where only a portion of the acid groups have been neutralized). Further, certain embodiments of the invention may use mixtures of complete and partial salts." See paragraph [0022].

Contrary to the Examiner's contention, Matthews et al do not teach or motivate a moisture or temperature sensitive composition. Even given the most generous interpretation, Matthews et al disclose a dipping method for a whitening composition that is tacky, the use of a tackifying agent to make a tacky composition sticky, like an adhesive, and a dipping method needed to dispense it. See paragraphs [0017]-[0022]. Neither a dispenser nor a composition of the present invention is thus disclosed or taught anywhere. In fact, Matthews et al.'s

tacky composition and dipping method completely teach away from the present invention. In paragraph [0023], Matthews et al. disclose that “(t)he amount of carboxypolymethylene within the dental whitening compositions may vary with the identities and concentrations of other ingredients with the whitening composition, as well as with the desired level of tackiness of the overall composition. In order to increase the stickiness, viscosity, and resistance to dilution to saliva, one may adjust the concentration of carboxypolymethylene to achieve a desired level of any or all of these properties.” (Emphasis added). If the composition of Matthews et al could increase its viscosity in a more humid environment, there will be no need to worry about dilution by saliva. Also, if the composition in Matthews is of a lower viscosity in the dispenser than in the mouth, as recited in the present invention, it would have been very difficult to transport the composition by a dipping method. The composition would have dripped off the dipping stick prior to arriving at the oral cavity. Therefore, the deficiencies in Green in view of Ding et al. are not provided by Matthews et al and claims 18, 38, and 42 are patentable under 35 U.S.C. 103(a) over Green in view of Ding et al. and further in view of Matthews et al. (2003/0232310).

Claims 34-37, 39, 40, and 51- 58 are dependent from claim 18, 38, and 42, respectively, and are rejected under 35 U.S.C. 103(a) as being unpatentable over Green in view of Ding and further in view of Matthews et al. (2003/0232310). While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that their rejections are moot in view of the remarks made in connection with independent claims 18, 38, and 42. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features which further distinguish the claims from the cited references. Therefore, claims 34-37, 39, 40, 42, and 51-58 are also patentable under 35 U.S.C. 103(a) over Green in view of Ding et al. and

further in view of Matthews et al. for at least the same reasons as discussed above.

Applicant respectfully requests that the rejection of claims 34-37, 39, 40, 42, and 51-58 under § 103(a) as being unpatentable over Green in view of Ding et al. and further in view of Matthews et al. be withdrawn. Reconsideration is respectfully requested.

4. Claims 34-37, 39, 40, 42, and 51-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Matthews et al. The modified device discloses a device that shows the limitations as described above; however, they do not show the composition comprising peroxide. Matthews et al. teach a device comprising a liquid oral therapeutic dental composition comprising therapeutic agent of hydrogen peroxide or carbamide peroxide [0020]-[0022]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device to have the therapeutic agent of Matthews et al. in order to whiten or bleach one or more teeth. Matthews et al. teach having instructions in order to show how to use the composition.

Applicant respectfully traverses the rejection.

As noted above, claims 18 and 38 are patentable over Grace (1,362,937) in view of Marx (1,041,315) and Ding et al. (6,541,020). Claim 42 is likewise also patentable over Grace (1,362,937) in view of Marx (1,041,315) and Ding et al. (6,541,020) for at least the same reasons as noted for claim 18 or 38.

As also noted above, Matthews et al.'s tacky composition and dipping method completely teach away from the present invention. In paragraph [0023], Matthews et al. disclose that "(t)he amount of carboxypolymethylene within the dental whitening compositions may vary with the identities and concentrations

of other ingredients with the whitening composition, as well as with the desired level of tackiness of the overall composition. In order to increase the stickiness, viscosity, and resistance to dilution to saliva, one may adjust the concentration of carboxypolymethylene to achieve a desired level of any or all of these properties.” (Emphasis added). Therefore, Matthews also teaches that exposure to a more humid environment can decrease and not increase the viscosity of the composition. Therefore, the deficiencies in Grace (1,362,937) in view of Marx (1,041,315) and Ding et al. (6,541,020) are not provided by Matthews et al.. If the composition of Matthews et al could increase its viscosity in a more humid environment, there will be no need to worry about dilution by saliva. Thus, claims 18, 38, and 42 are patentable under 35 U.S.C. 103(a) over Grace (1,362,937) in view of Marx (1,041,315) and Ding et al. (6,541,020), further in view of Matthews et al. (2003/0232310).

Claims 34-37, 39, 40, 42, and 51-58 are dependent from claims 18, 38, and 42 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Matthews et al. Applicant respectfully submits that as they are dependent from claims 18, 38, and 42, they are also patentable for at least the same reasons as noted for claims 18, 38, and 42 above. Reconsideration is respectfully requested.

5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Dragan (6,929,475).

The modified device discloses a device that shows the limitations as described above; however, they do not show plurality of bristles aligned generally parallel with lengthwise direction of the device. Dragan teaches a dental device comprising an applicator with plurality of bristles 246 aligned

generally parallel with lengthwise direction of the device the composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device to have the applicator of Dragan in order to apply material between teeth and to gum at base of the teeth in view of Dragan.

Applicant respectfully traversed the rejection.

As noted above, claim 18 is patentable over Grace in view of Marx and Ding et al.

Dragan et al. teach an applicator pre-dosed with a material, such as a chemical or a medicament. The material is placed on an absorbent portion of the applicator and permitted to dry. The material is then in an inactive, stable state on the applicator, and is re-activated upon being exposed to water, saliva, liquids, or other activating materials, See Col. 1, Line 35-42. Thus, Dragan et al do not teach a liquid oral therapeutic dental composition, said therapeutic dental composition comprises a moisture or temperature responsive composition that increases in viscosity in a more humid environment (Emphasis added). On the other hand, Dragan's disclosure of using liquid to get a material out of a dry state, i.e., dissolving the solid or lowering the viscosity of the material in a more humid environment, is teaching away from the present invention, since going from a dry state to a wet state involves a dilution, i.e. a decrease, not an increase, in viscosity. Thus, the deficiencies in Grace in view of Marx and Ding et al. are not supplied by Dragan, for the reasons noted above. Therefore, claim 18 is also patentable over Grace in view of Marx and Ding et al., and further in view of Dragan.

Claim 31 is dependent from claim 18 and is rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Dragan (6,929,475). While Applicant does not acquiesce with the

particular rejections to these dependent claims, it is believed that their rejections are moot in view of the remarks made in connection with independent claim 18. The dependent claim includes all of the limitations of the base claim and any intervening claims, and recites additional features which further distinguish the claim from the cited references. Therefore, claim 31 is also patentable under 35 U.S.C. 103(a) over Grace in view of Marx and Ding et al. and further in view of Dragan.

Applicant respectfully requests that the rejection of claim 31 under § 103(a) as being unpatentable over Grace in view of Marx and Ding et al. in further view of Dragan be withdrawn. Reconsideration is respectfully requested.

#### **IV. CONCLUSION**

In view of the amendments and remarks set forth above, Applicant respectfully submits that the application is in condition for allowance and early notice thereof is respectfully solicited.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-621-6415.

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